

REMARKS

Claims 1-32 are pending and ready for examination on the merits. Claims 1, 11, 17, 24 and 31 have been amended. No new matter is added by the amendments. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the remarks set forth below.

Claim Rejections – 35 U.S.C. § 112

Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner stated that the independent claims recite several steps which include the terms “activating” and “determining” but that the claims and the specification do not provide any particular structure or method by which to perform these steps. Applicant respectfully disagrees.

With regard to the term “activating,” Applicant would like to draw the attention of the Examiner to at least paragraphs [0018] – [0022] of the specification wherein the authentication process is further detailed. In short, these paragraphs state that “[t]he system employs authentication codes, such as machine readable codes including bar codes, or radio frequency (RF) tags, which can be applied to any level of packaging of the products to be transported from the manufacturer, including single dosage packages. A system server/database issues a number of authentication codes to a manufacturer, and the manufacturer applies the codes to product packaging and/or containers for shipment.” *Specification* at paragraph [0022].

The specification continues, “When the products are ready for shipment, the manufacturer activates the codes (or code, depending on how many are used) by reading the authentication code with a code reader, and transmitting the code along with additional information about the product such as expiration date, type of product or medication, and shipment information such as destination and time for shipment, for example, to the system server/database.” (Emphasis added). Communication with the system server/database can take place over a secure web link, for example, to ensure the security of the authentication code being activated. *Id* at paragraph [0018].

With regard to the term “determining,” the specification states, “[w]hen the manufacturer ships the products directly to the provider, the provider can verify that the products received are those that were shipped by the manufacturer by reading the authentication codes on the shipping

container, package, or single dose packages using a code reader. The code is transmitted to the system server/database, along with information regarding the provider location, and the system server/database provides verification as to whether the code read at the provider corresponds to the code activated by the manufacturer, and whether the provider location matches the destination location corresponding to the activated code.” *Id* at paragraph [0019].

Once the activated authentication code is read at the final destination specified by the manufacturer and stored in the server/database, the code is then expired in the system server/database. “Substitute or counterfeit products can thus be identified because only the products received at the provider having the active authentication code will correspond to the authentication code activated by the manufacturer and stored in the system server/database. Attempts by a provider to authenticate a product having an expired authentication code will fail, thus notifying the provider that the product may be counterfeit.” *Id* at paragraph [0020].

The specification also enables the situation when there are intermediate destinations in the distribution chain of a pharmaceutical product by disclosing that “authenticity can be verified at every location along the distribution chain. In addition, the location of the product can be tracked, as each time the activated authentication code is read by a code reader requesting verification from the system server/database, the physical location of the code reader that makes the request can be stored at the system server/database. Alternately, if a substitute or counterfeit authentication code is read by a code reader at an intermediate destination, the system server/database can indicate that the authentication code has not been activated by a manufacturer and is invalid. The server/database can notify the manufacturer and provider that a substitute product has attempted to enter the distribution chain.” *Id* at paragraph [0021].

The specification discloses further explanation regarding the verification process stating, “[v]erification of an authentication code preferably includes correlation of at least one data element or informational element in addition to the authentication code, such as a product’s intended destination. The data element or informational element is also preferably unrelated to or indiscernible from product packaging. Thereby, a would-be counterfeiter would only be able to copy one element (the authentication code) necessary for verification of a product from product packaging, and the additional data element would remain unknown. The additional data element or informational element is not limited to the intended destination or destinations of a

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product, and other types or categories of information are contemplated. In addition, the type or category of information used by the tracking system for verification of an authentication code may be altered periodically.” *Id* at paragraph [0022].

Accordingly, the claims are in compliance with the enablement requirement and Applicant respectfully requests that the rejection of Claims 1-32 be withdrawn.

Claim Rejections – 35 U.S.C. § 101

Claims 11-16 and 24-32 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Specifically, Claims 11-16 and 24-30 were rejected for lacking an apparatus that accomplishes the method steps or for not transforming the underlying subject matter to a different state or thing. *Office action* at page 3.

In *In re Bilski*, the Federal Circuit held that the test for whether a process claim is directed to statutory subject matter is whether the claimed subject matter satisfies the “machine-or-transformation test.” *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008). Statutory subject matter is subject matter which is 1) tied to a particular machine or apparatus, or 2) transforms a particular article to a different state or thing. *Id.*

Claims 11, 24 and 31 have been amended to recite a data storage and a processor, as described in the specification. Accordingly, Claims 11, 24 and 31, which claim an apparatus, are directed to statutory subject matter under 35 U.S.C. § 101. Therefore, Applicant respectfully requests the rejections be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1-17, 21 and 23-32 are rejected under 35 U.S.C. § 103(a), as being unpatentable over Michael, et al (U.S. 2003/0088442) in view of Cunningham (U.S. 6,859,780 B1) in further view of Moore (U.S. 6,456,729). Applicant respectfully submits that pending Claims 1-17, 21 and 23-32 are allowable over the prior art of record as discussed below.

Standard of Prima Facie Obviousness

The Patent and Trademark Office has the burden under section 103 to establish a *prima facie* case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-87 (Fed. Cir. 1984). To establish a *prima facie* case of obviousness, however, prior art (as opposed to

prior art references) must teach or suggest all the claim limitations. "Examination Guidelines for Determining Obviousness Under 35 U.S.C. §103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" Federal Register Vol. 72 No. 195 at 57528 (October 10, 2007). Further, the Patent Office must explain why the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. *Id.*

Discussion of Patentability of Independent Claim 1

Michael is directed to a system and method for tracking inventory in an environment in which workers and inventory are mobile and distributed across a wide geographic area. *Michael* at [0002]. The disclosure is directed to automatically tracking pharmaceutical samples from the pharmaceutical company representative to doctors. *Id* at [0023]. The system disclosed is directed to allowing a pharmaceutical representative to receive a shipment of samples and then log those samples into a sub database before distributing them to doctors' offices. However, in contrast to Applicant's claims, the samples are not tracked from the source to a known destination, but rather from the pharmaceutical representative's inventory to distribution to a doctor. Further, the samples distributed in Michael's system are tracked, but not authenticated. The purpose of the tracking in Michael is to ensure that samples travel from the representative to an actual doctor's office and not, as in Applicant's claims, to ensure that the pharmaceutical product, as it arrives at its intended destination, is authentic (for example, and not counterfeit).

The Examiner admits, and Applicant agrees, that Michael does not disclose the feature wherein said activation computer is further configured to activate said authentication codes for pharmaceutical packages that are being sent to destination sites. Instead, the Examiner states that Cunningham discloses the above-recited feature.

Cunningham discloses a method of dispensing, tracking and managing pharmaceutical product samples by communicatively linking prescribers and pharmacies to a central computing station. Cunningham discloses a method whereby "to identify various pharmaceutical trial products, the system utilizes a medium, such as a magnetic card, which is encoded with specific information that particularly identifies a certain pharmaceutical trial product. Enclosed media is then distributed to participating medical doctors or prescribers. Once the encoded product trial media is received by the prescribers, the prescribers then activate the selected product trial media

. . . Once the product trial media has been activated, the prescriber then transfers the activated product trial media to patients. The patients then present the activated product trial media to participating pharmacies." *Cunningham* at column 3 lines 10-23.

Thus, Cunningham is directed to a system whereby the *pharmaceutical product* is not shipped with an authentication code, as is recited in Applicant's claims; but rather a magnetic card is encoded and shipped. While this system ensures that a doctor prescribes the sample to a patient, it does not in any way reflect the authenticity of the pharmaceutical product that the patient receives from the pharmacy. Applicant's Claim 1 recites a system in which the authentication codes are read from pharmaceutical packages. Cunningham discloses a system wherein a code is presented on a card or other media, taken to a doctor to be authenticated and then prescribed to a patient who presents the activated media at a pharmacy. Cunningham is directed to making sure that the *patient* is a person with a valid need for the pharmaceutical product. In contrast, Applicant's claims are directed to ensuring that the *pharmaceutical product* is valid, not expired or is otherwise authentic.

With regard to Michael and Cunningham, there is no motivation to combine the inventory management system of Michael and the code activation technique of Cunningham with Applicant's system because to do so would defeat the very purpose of the activation: that is, to control and track pharmaceuticals such that the pharmaceutical products ends up in the possession of the recipient, and not resold, diverted or counterfeited in the chain of custody before reaching the intended recipient. In contrast, both Michael and Cunningham are directed to control of who receives the pharmaceutical product and not the authenticity of the product itself.

The Examiner further admits, and Applicant agrees, that the neither Michael nor Cunningham discloses the feature recited in Claim 1 of an authentication computer configured to receive authentication codes that are read from pharmaceutical packages received at said destination sites and determine whether said authentication codes have been activated. However, the Examiner states that Moore discloses the above-recited feature.

Moore is directed to affording manufacturers the ability to eliminate problems which begin at one or more manufacturing sites which are remote from central control. *Moore* at abstract. The passage cited by the Examiner in Moore discloses "[t]he products are identified and verified by using a light of appropriate wavelength to illuminate the symbol on the products.

The illuminated symbol is captured by the camera. The captured image is then transferred to a portable PC where the data is enhanced if necessary, compressed, and transmitted via modem, cellular link, or satellite communication to the host." *Moore* at column 6 lines 14-20. Applicant respectfully submits that the *activating* of a code as in Applicant's claims and the *validating* of a code as in *Moore*, are very different. *Moore* discloses a system wherein the same article of manufacture can be scanned and deemed to be valid at any given number of checkpoints via the use of cameras, decoders and the like. Applicant's claims are directed to activating a code *prior to* its departure with a *known intended recipient and route* and scanning the product at its destination to verify the product activation at its destination. This activation happens once, whereas the validation of the item can happen multiple times without regard to previous scans. Thus, *Moore* is merely directed to validating an item of manufacture along a shipping route.

Claim 1 has been amended to recite the feature wherein the authentication computer is configured to flag said activated authentication code as expired in response to a successful verification of said authentication code. Independent Claim 17 has been amended to recite the feature wherein the activation module is configured to deactivate said active authentication code in response to a successful verification of said authentication code. Indcpentent Claim 24 has been amended to recite the similar feature of flagging said active authentication code as expired in response to a successful verification of said authentication code. The Examiner states that these features are disclosed in Cunningham. *Office action* at page 10. Applicant respectfully disagrees.

Cunningham is characterized and described in the above paragraphs. With regard to the above-recited feature, the passage cited by the Examiner discloses that the media "act as the prescription form and may include a field that indicates the pharmaceutical product to be prescribed, a quantity of pharmaceutical product complete with size of dosage if appropriate, and a number of validations available. The number of validations is representative of the number of refills that may be obtained. As the patient acquires the refills, the number of refills or validations field is decremented." The Examiner is equating the validation field in Cunningham to the activation authentication code recited in Claim 1. However, the authentication code recited in Claim 1 is activated before the package is sent and is flagged as expired upon a successful verification at the destination site because the package has arrived safely. In contrast

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to Cunningham, Applicant's claims are directed to the authentication at receipt of the *pharmaceutical product* at its intended destination and not the prescription control of the product by users and pharmaceutical representatives as is Cunningham.

Nowhere in Michael, Cunningham or Moore is an activation code disclosed where the wherein the authentication computer is configured to flag said activated authentication code as expired in response to a successful verification of said authentication code.

Discussion of Patentability of Independent Claims 11, 17, 24 and 31

Claims 11, 17, 24 and 31 contain limitations substantially corresponding to those discussed above with respect to Claim 1. Accordingly, for at least the reasons set forth above in reference to independent Claim 1, Applicant respectfully submits that Claims 11, 17, 24 and 31 also define subject matter which is patentable over Michael, Cunningham and Moore, taken individually or in combination.

Discussion of Patentability of Dependent Claims

The Examiner has rejected Claims 2-10, 12-16, 25-30 and 32 under U.S.C. § 103(a) as being unpatentable over Michael in view of Cunningham, in further view of Moore. The Examiner has rejected Claims 18-20 and 22 under U.S.C. § 103(a) as being unpatentable over Michael in view of Cunningham, in further view of Moore in further view of official notice. Further, Claims 2-10, 12-16, 18-23, 25-30 and 32 depend from base Claims 1, 11, 17, 24 or 31 and further define additional technical features of the present invention. In view of the patentability of their base claims, and in further view of the additional technical features, Applicant respectfully submits that the dependent claims are patentable over the prior art. Furthermore, Applicant does not necessarily agree with the characterizations of the prior art made by the Examiner in rejecting the dependent claims, but defers further argument in view of their current allowable status.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this

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application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants have endeavored to address all of the outstanding concerns indicated by the Examiner in the most recent Office Action. If any concerns or questions remain, the Examiner is hereby invited to call the undersigned at the phone number listed below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 19, 2009

By:



Jason J. Jardine
Registration No. 61,805
Attorney of Record
Customer No. 20,995
(619) 235-8550

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